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ATTACHMENT 3.1-E
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State/Territory: Missouri

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

Human Organ and Bone Marrow Transplants and Related Transplantation Services -

For human organ or bone marrow transplants and related transplantation services as specified in this part, pages 1a - 1e, the State agency has written standards regarding the provision of these services and benefits available. These standards are included, and further incorporated by reference in this attachment, as in state rule 13 CSR 70-2.200.

Standards applicable to corneal transplant services restrict performance of the surgical procedures to physicians with a provider specialty of "17" or "18" - ophthalmology. Corneal transplant services are restricted to an outpatient place of service unless the provider is able to justify inpatient admission through the admission certification review process conducted by the review authority.

The standards are applied on a case-by-case basis in a manner which insures that individuals similarly situated receive similar treatment and that any restrictions imposed under the standards on the facilities and practitioners are consistent with the accessibility of high quality to eligible individuals.

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STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

(1) Administration.

Through its Medicaid Program, the Department of Social Services (DSS)/Division of Medical Services (DMS) will provide limited coverage and reimbursement for the transplantation of human organs or bone marrow and the related medical services, including, but not necessarily limited to, treatment and necessary pre-transplant and post-operative care for the specific procedures defined herein and subject to the conditions and limitations as specified herein and as further defined by DSS/DMS and included in the provider program manuals.

- (A) The recipient must be Medicaid-eligible on each date on which services are rendered.
- (B) Medicaid shall be the payor of last resort and all other appropriate funding sources must be exhausted prior to obtaining Medicaid reimbursement.

(2) Conditions and Limitations.

- (A) The procedures of transplantation and the related medical services must be "Prior Authorized" by DSS/DMS.
- (B) Medicaid benefits may be provided for transplantation of the following:
 - 1. Bone Marrow;
 - 2. Heart;
 - 3. Kidney;
 - 4. Liver; and
 - 5. Lung (effective for dates of service October 1, 1991, and after that date).
- (C) Transplants which include multiple organs, at least one of which is covered under subsection (2)(B), may be covered at the recommendation of the Transplant Advisory Committee.

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- (D) Each request for coverage will be handled on a case-by-case basis. A separate "Prior Authorization Request" must be submitted for each individual recipient and transplant.
- (E) In order to be considered for approval, each proposed transplant case must meet all of the requirements of procedures and protocols specific to the service as defined by DSS/DMS. Such procedures and protocols will be developed with input by the DMS' "Transplant Advisory Committee".
- (F) Approved organ transplants can only be performed in a facility which submits documentation approved by DMS as complying with the following criteria:
1. The transplant facility must qualify for membership in the national transplantation network and must provide a copy of a current effective certification from the United Network for Organ Sharing (UNOS) granting approval to perform specific transplant(s). The certification from UNOS will be considered appropriate verification and documentation for DMS transplant facility approval.
 2. When the period for initial certification expires, the transplant facility must provide to DMS evidence that continued approval from UNOS allowing participation to perform the transplant(s) has been granted.

Each UNOS expiration period must be documented by renewed approval from UNOS to continue approval as a Missouri Medicaid Transplant Facility.
 3. Each type of Missouri Medicaid covered organ transplant will be subject to separate UNOS certification for each type of organ transplant.
 4. The transplant facility must notify DMS of each new transplant surgeon who becomes a member of the transplant team. The transplant surgeons must be current Missouri Medicaid participating providers.
 5. The transplant facility must name the organ procurement organization (OPO) presently utilized by the facility. The transplant facility must furnish a copy of the notification from Health Care Financing Administration (HCFA) which designates the facility's OPO as an acceptable organ procurement source.
 6. The transplant facility must provide DMS with a yearly report of the number of patients receiving transplants at the facility and the average charge for the inpatient transplant stay (by type of transplant(s) performed) as defined by DMS in the provider program manual.

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7. Those facilities seeking certification as a Medicaid-Approved Kidney Transplant Center must furnish a copy of their current Medicare certification indicating active participation in the "Medicare Renal Transplant Program."
 8. The facility must submit a copy of their "Protocol for Transplantation Cases" and "Patient Selection Criteria" for the type of transplant for which they are requesting transplant facility approval.
- (G) Approved bone marrow transplants can only be performed in a facility which submits documentation approved by DMS as complying with the bone marrow transplant facility criteria. An autologous only transplant facility must meet criteria items one through twelve.
1. Physician(s) with expertise in pediatric and/or adult bone marrow transplantation, hematology and oncology.
 2. Identified nursing unit with protective isolation unit for bone marrow transplantation.
 3. Blood bank with Pheresis capability and the capability to supply required blood products or association with a qualified blood bank.
 4. Physicians with expertise in infectious disease, immunology, pathology and pulmonary medicine.
 5. Capability of providing cardiac/respiratory intensive care and renal dialysis.
 6. Must have performed at least 13 bone marrow transplants a year or demonstrated an ability to care for prolonged marrow failure by treating 22 marrow failure patients per year.
 7. Capability for marrow Cryopreservation and purging techniques or affiliation with a facility which has these capabilities.
 8. Capability to provide psycho-social support to patients and their families.
 9. Close affiliation with academically based institutions to insure that all components of comprehensive care for patients undergoing bone marrow transplantation are present in the facility. The mere presence or availability of the components one (1) through eight (8) is not adequate. The facility must demonstrate that a coordinated bone marrow transplantation program is in place, and directed by a physician trained in an institution with a well established bone marrow transplantation program.
 10. The capacity and commitment to conduct a systematic evaluation of outcome and cost. Refer to subsection (F)(6).

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11. Once approved, continuing approval of the facility requires evidence of a record of success and safety with bone marrow transplantation, and that the program continues to meet the above criteria.
 12. The facility must submit a copy of their "Protocol for Transplantation Cases" and "Patient Selection Criteria" for the type of bone marrow transplants to be performed at the facility. Once approved as a facility each new type of bone marrow transplant or diagnosis added for treatment by the facility must be documented by submitting the new Protocol and Patient Selection Criteria.
 13. Physicians with expertise in infectious disease, immunology, pathology (of Graft vs. Host Disease), and pulmonary medicine.
 14. Tissue typing laboratory with capability to perform typing for HLA-A, B, C, D/DR, and MLC.
 15. Cytogenetic laboratory.
 16. Adequate laboratory facility to assay drug levels including Cyclosporine A.
- (H) All providers of transplantation and related services must sign a "Missouri Medicaid Provider Participation Agreement" in order to receive reimbursement.
- (I) In the case of a medical emergency, submittal of the required facility documentation may be waived for a period of 90 days. During that period, the facility must submit the appropriate documentation as described in subsections (2)(F) or (2)(G), (2)(J), and (3)(A) -- and they shall be financially "at risk" regarding state approval for any transplant related services rendered prior to the approval of their application.
- (J) The transplant facility or surgeon must submit medical documentation that verifies that the transplant candidate has met the facility's Patient Selection Criteria documented by the facility's "Protocol for Transplantation Cases."
- (K) All transportation and housing costs incurred in connection with transplant procedures will be treated as "Non-Covered Services."
- (L) The transplant procedures and related services outlined above will be reimbursable when they are performed/provided by a qualified provider who participates in the Missouri Medicaid Program. In cases involving procedures that are to be performed outside of Missouri, however, the "Transplant Advisory Committee" may, at its discretion, require an eligible client's physician to file a statement indicating why the transplant procedure must be performed at an out-of-state facility.

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(M) DSS/DMS will reimburse qualified providers for a "Pre-surgery Assessment" at established Medicaid reimbursement rates.

(3) Procedure.

(A) The physician or transplant facility must make a written request to DSS/DMS for coverage of the transplant. This request must include, at a minimum, the following information:

1. Diagnosis;
2. Pertinent medical history;
3. Alternative treatments performed and results;
4. Recommended transplant procedure;
5. Prognosis;
6. Results of a "pre-surgery assessment" and copies of medical documentation verifying that the patient has completed the selected facility's "protocol for the selection of transplant recipients";
7. Name of the selected transplant center. In cases involving out-of-state facilities, a statement from the patient's physician explaining why the transplant procedure must be performed there. (Note: Such statements may be requested at the discretion of the DMS "Transplant Advisory Committee");

(B) The request for transplantation will be reviewed by DMS and the transplant facility advised in writing of the decision. An agreement will be issued on a case-by-case basis for approved transplants.

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